

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PHARMACYCLICS LLC and)	
JANSSEN BIOTECH, INC.,)	
)	
Plaintiffs,)	
)	
v.)	Civ. No. 18-192-CFC/CJB
)	(CONSOLIDATED)
CIPLA LIMITED, et al.,)	
)	
Defendants.)	
<hr style="border: 1px solid black;"/>		
PHARMACYCLICS, LLC and)	
JANSSEN BIOTECH, INC.,)	
)	
Plaintiffs,)	
)	
v.)	Civ. No. 19-434-CFC/CJB
)	
ALVOGEN PINE BROOK, LLC)	
and NATCO PHARMA LTD.,)	
)	
Defendants.)	

MEMORANDUM ORDER

Pending before me is Plaintiffs' request to preclude Sandoz (i.e., Defendants Sandoz, Inc. and Lek Pharmaceuticals d.d.) from maintaining its theory that because U.S. Patent No. 10,106,548 (the #548 patent) did not disclose as inventors unidentified employees of Pharmorphix the patent is invalid under 35 U.S.C. § 102(f).

Sandoz first disclosed its Pharmorphix inventorship theory to Plaintiffs on September 4, 2020 when it sent Plaintiffs a draft of Sandoz's portion of the Pretrial Order (PTO). Sandoz argues that it disclosed the facts underlying this theory in its final invalidity contentions served in January 2020, but I don't think that's a fair reading of its contentions.¹ In any event, mere disclosure of facts underlying an

¹ Sandoz's only mention of Pharmorphix in its final contentions occurred in the context of its contention that the #548 patent and other asserted polymorph patents are invalid for incorrect inventorship because they list inventors, including Dr. Smyth, who did not contribute to the claimed inventions. The contention reads in relevant part:

Likewise, Dr. Smyth could not even recall if [he] contributed to isolating Form A. Dr. Smyth testified that his only contribution to the [#]753 Patent was to lead the technical work on the project and that he did not have any laboratory rol[e]. Dr. Smyth testified that the third party contract laboratory Seres used SSCI as an analytical laboratory for the polymorph analysis. Dr. Smyth further testified that Pharmacyclics engaged SSCI directly to perform the polymorphic analysis in 2008, and that SSCI formulated the approach for the polymorph screen, and conducted the polymorph screen. Dr. Smyth further testified that Pharmacyclics engaged Pharmorphix to conduct a second polymorphic screen, and that Pharmacyclics did not contribute anything other than some cost control. Therefore the Asserted Claims of the Polymorph Patents are invalid pursuant to 102(f) for incorrect inventorship because they list inventors who did not contribute to the claimed inventions: Mr. Purro, Mr. Goldman, and/or Dr. Smyth.

D.I. 509, Ex. B at 319 (citations omitted). The point of this assertion is that the patents in question are invalid because of misjoinder (i.e., the erroneous naming of a noninventor as an inventor) as opposed to nonjoinder (i.e., the erroneous

invalidity theory does not constitute a disclosure of the theory. The purpose of final invalidity contentions is to give fair notice to the patentee of the theories of invalidity the accused infringer will pursue at trial. Notice of the facts underlying those theories is insufficient. In this case, Sandoz disclosed its invalidity theory as consisting of the following syllogism: (1) “the polymorph patents name multiple incorrect inventors”; (2) “at least one unnamed SSCI employee is a coinventor of the polymorph patents”; (3) “plaintiffs will be unable to correct the inventors for the polymorph patents pursuant to 35 U.S.C. § 256”; and (4) “the [#]548 patent was derived from another and is therefore invalid pursuant to section 102(f).” D.I. 509, Ex. B at 318–22 (capitalization omitted). It is simply not credible to argue that this disclosure put Plaintiffs on notice that Sandoz’s inventorship theory was based on inventorship contributions made by Pharmorphix, as opposed to SSCI, employees.

Sandoz argues that Plaintiffs waived their right to object to Sandoz’s pursuit of its Pharmorphix inventorship theory. But the relevant waiver was made by Sandoz, not Plaintiffs. By failing to seek Plaintiffs’ consent or leave from the

omission of the name of an inventor). *See CODA Dev. S.R.O. v. Goodyear Tire & Rubber Co.*, 916 F.3d 1350, 1358 (Fed. Cir. 2019) (distinguishing between misjoinder and nonjoinder). Sandoz did not assert that a Pharmorphix employee was an inventor, but rather that Dr. Smyth did not contribute sufficiently to be an inventor.

Court to amend its final contentions, Sandoz waived its right to present at trial an invalidity theory not disclosed in its final contentions.

In any event, I find that Plaintiffs did timely object to Sandoz's attempt to assert at trial its Pharmorphix inventorship theory. Sandoz did not mention its Pharmorphix inventorship theory during its opening argument. The first time at trial Sandoz sought to adduce evidence that could be used to support such a theory, Plaintiffs objected. *See* Trial Tr. 842:3–845:11. Because it was a bench trial and because Sandoz represented that the evidence was also relevant to other issues at trial, I allowed the evidence to be conditionally admitted and held that Plaintiffs' objection preserved their ability to seek to preclude after trial my consideration of Sandoz's inventorship theory.

Sandoz points to the fact that the Pharmorphix inventorship theory is mentioned in the PTO and that Plaintiffs failed to object in the PTO or by a motion in limine before trial to the inventorship theory on the basis that the theory was not set forth in Sandoz's final invalidity contentions. But given the number of contested facts and issue of law Sandoz identified in the 8,629-page PTO, I would not fault Plaintiffs if they failed to appreciate in the throes of last-minute trial preparation that the Pharmorphix inventorship theory was beyond the scope of Sandoz's final contentions.² Nor do I fault Plaintiffs for not seeking leave to file a

² Sandoz makes much of the fact that Plaintiffs stated in emails with Sandoz after

motion in limine or for not otherwise burdening the Court before trial with an objection to one of the many defenses Sandoz identified in the PTO when Plaintiffs did not know if Sandoz would ultimately pursue that defense at trial.³ The truth is that neither side had definitively narrowed in the PTO the theories it intended to pursue at trial. This fact was openly discussed at the pretrial conference. *See* Tr. of Sept. 23, 2020 Hr'g at 72:3–83:3..

Finally, Sandoz argues that “[w]here a defendant fails to sufficiently identify an invalidity defense in its contentions, the court should not exclude the defense if ‘the failure was substantially justified or is harmless.’” D.I. 507 at 4 (quoting *Boehringer Ingelheim Int'l GMBH v. Barr Labs., Inc.*, No. CIV. A. 05-700-JJF, 2008 WL 2756127, at *2 (D. Del. July 15, 2008)); *see also* Fed. R. Civ. P. 37(c)(1). In this case, however, Sandoz’s failure was not substantially justified; nor can it be called harmless. With respect to justification, Sandoz claims that “[i]t was not until Dr. Myerson’s rebuttal expert report on invalidity, served in late May 2020, where Plaintiffs first asserted that Form D fell within the scope of Claims 15 and 16 of the [#]548 patent.” D.I. 507 at 5–6. But even assuming that Dr.

the PTO was filed that Sandoz’s inventorship theory was outside the scope of expert reports. It appears undisputed that the Pharmorphix inventorship theory was not disclosed in expert reports and I do not think such statements waived Plaintiffs’ right to object to the Pharmorphix inventorship theory on the grounds that the theory was not disclosed in Sandoz’s final contentions.

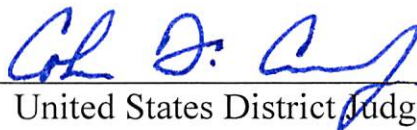
³ Sandoz identified nine invalidity and noninfringement theories in the PTO that it ended up not pursuing at trial.

Myerson's rebuttal report was the impetus for Sandoz's decision to pursue its Pharmorphix inventorship theory, Sandoz offers no explanation that would justify it waiting until September to disclose to Plaintiffs that it intended to pursue the theory at trial. To this day, Sandoz has not demonstrated that good cause exists to allow it to amend its final contentions. With respect to harm, Sandoz's late disclosure of its inventorship theory deprived Plaintiffs of the opportunity to seek relevant documents and testimony from Pharmorphix and to search through its own production for documents that might be used to rebut the theory.

In short, Sandoz's disclosure of its inventorship theory on the eve of trial and almost eight months after it served its final contentions was unjustified, prejudiced Plaintiffs, and deprived Plaintiffs of the opportunity to cure any prejudice. Sandoz's explanation for its late disclosure is suspect, though I find it unnecessary to decide whether it acted in bad faith. The balance of relevant factors weighs in favor of Plaintiffs' request to preclude Sandoz from pursuing its Pharmorphix inventorship theory, and accordingly I will grant that request.

11.10.20

Date


United States District Judge